

§ 1301.35 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1301.36 and has no bearing on whether the application will be granted.

§ 1301.36 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

§ 1301.37 Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.48. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 60 FR 32101, June 20, 1995]

§ 1301.38 Special procedures for certain applications.

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing agency, the applicant may include with his application an affidavit as to the existence of the State license in the following form:

AFFIDAVIT FOR NEW PHARMACY

I, _____, the _____
(Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) at _____ (Number and Street), _____ (City) _____ (State) _____ (Zip code), hereby certify that said store was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ on _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000 or both.

Signature (Person who signs Application for Registration)
State of _____
County of _____
Subscribed to and sworn before me this _____ day of _____, 19____.

Notary Public

(b) Whenever the ownership of a pharmacy is being transferred from one